



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0192]

Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of U.S. Milk Product Manufacturers/Processors With Interest in Exporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency.

Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection entitled “Establishing and Maintaining Lists of U.S. Milk Product Manufacturers/Processors With Interest in Exporting,” which establishes and maintains lists of U.S. milk product manufacturers and processors with interest in exporting to countries that require such lists to be maintained. The notice also solicits comments on an electronic registry that will allow manufacturers and processors of milk products to electronically request inclusion on the export lists.

DATES: Submit either electronic or written comments on the collection of information by

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2014-N-0192 for “Establishing and Maintaining Lists of U.S. Milk Product Manufacturers/Processors with Interest in Exporting.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing

and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to

provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Establishing and Maintaining Lists of U.S. Milk Product Manufacturers/Processors With Interest
in Exporting--21 U.S.C. 371

OMB Control Number 0910-0509--Extension

The United States exports a large volume and variety of foods in international trade. For certain food products, foreign governments may require assurances from the responsible authority of the country of origin of an imported food that the processor of the food is in compliance with applicable country of origin regulatory requirements. With regard to U.S. milk products, FDA is the competent U.S. food safety authority to provide this information to foreign governments. FDA provides the requested information about processors in the form of lists, which are provided to the foreign governments and posted online at <http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/default.htm>.

Currently, FDA provides Chile, China, and the European Union (EU) with a list of U.S. milk product manufacturers/processors that: (1) Have expressed interest in exporting their products to these countries; (2) are subject to FDA's jurisdiction; and (3) are not the subject of a pending enforcement action (i.e., an injunction or seizure or a pending warning letter).

FDA has published guidance documents for these countries under the authority of section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)), which authorizes the Secretary of Health and Human Services (the Secretary) to develop guidance documents with public participation presenting the views of the Secretary on matters under the jurisdiction of FDA.

The guidance documents explain what information manufacturers/processors should submit to FDA to be considered for inclusion on the lists and what criteria FDA intends to use to determine eligibility for placement on the lists. The guidance documents also explain how FDA intends to update the list and communicate any new information to the government that requested the list. Finally, the guidance documents note that the information is provided voluntarily by manufacturers/processors with the understanding that it will be posted on FDA's external Web site and communicated to, and possibly further disseminated by, the government that requested the list; thus, FDA considers the information on the lists to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4).

Application for inclusion on each list is voluntary. However, some foreign governments may require inclusion on the list for acceptance of imported food. FDA recommends that U.S. manufacturers/processors that want to be placed on the export lists send FDA the following information: (1) Country to which the milk manufacturer/processor wants to export product; (2) type of milk product facility; (3) the Food Facility Registration Module number (the information

collected by this module is approved under OMB control number 0910-0502); (4) name and address of the firm and the manufacturing plant; (5) name, telephone number, and email address of the contact person; (6) list of products divided into three categories: Presently shipped, ready to ship, and available for shipment in the next 3 years; (7) identities of agencies that inspected the plant; (8) date of last inspection, plant number, and copy of last inspection notice; and (9) if other than an FDA inspection, copy of last inspection report.

We request that this information be updated every 2 years.

We use the information submitted by firms to determine their eligibility for placement on the export lists, which are published on our Web site. The purpose of the lists is to help foreign governments in their determinations of which U.S. milk product manufacturers and processors are eligible to export to their respective countries.

FDA has recently developed an electronic registry system (Form FDA 3972) that allows milk product manufacturers and processors to electronically send a request to FDA to be included on the export lists. Manufacturers and processors that prefer to submit a paper request in a format of their own choosing will still have the option to do so. Electronic Form FDA 3972 collects the same information as is currently collected via the existing paper-based process. Draft screenshots of Form FDA 3972 and instructions are available at <http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm496929.htm> and is entitled "Dairy Listing Module."

Description of Respondents: Respondents to this collection of information include U.S. milk product manufacturers/processors subject to FDA jurisdiction that wish to export to certain foreign countries that require inclusion on export lists.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
New requests to be placed on the lists	2,000	1	2,000	1	2,000
Biennial update	2,000	1	2,000	0.5 (30 minutes)	1,000
Occasional updates	200	1	200	0.5 (30 minutes)	100
Total					3,100

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimate on the number of manufacturers/processors that have submitted new written requests, biennial updates, and occasional updates over the past 10 years. The estimate of the number of burden hours it will take a manufacturer/processor to gather the information needed to be placed on the list or update its information is based on FDA's experience with manufacturers/processors submitting similar requests. FDA believes that the information to be submitted will be readily available to manufacturers/processors. This collection is also incorporating information collected to maintain lists of eligible exporters of dairy products who wish to export to the EU from OMB control number 0910-0320, "Request for Information from U.S. Processors that Export to the European Community."

FDA estimates that 2,000 firms will average 60 minutes (1 hour) to submit new requests for inclusion on the list, 2,000 firms will average 30 minutes (0.5 hour) to update their information every 2 years, and 200 firms will average 30 minutes (0.5 hour) to occasionally update their information in this system. We also believe that submission via the electronic registry system will not affect the burden estimates. An electronic registry will enhance the ability of firms to more efficiently request inclusion on export lists. FDA calculates, therefore, that the total burden for this collection is 3,100 hours $((2,000 \times 1) \text{ plus } (2,000 \times 0.5) \text{ plus } (200 \times 0.5))$.

Dated: June 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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